CHALLENGES TO VACCINE ACCESS: SII PERSPECTIVE

Global Challenges Seminar on Vaccines: accelerating innovation and access
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WIPO, Geneva 8 November 2017
Factors that condition access to vaccines in countries

Epidemiologic, financial, Logistic, programmatic considerations

COST/BENEFIT (competing priorities)

COUNTRY PREPAREDNESS

SUSTAINABLE FINANCING

ACCESS

VACCINE AVAILABILITY

R & D

REGULATORY CHALLENGES

TPP

Investment

Sustainability

November 9, 2017
CHALLENGES FOR VACCINE DEVELOPMENT

Serum Institute of India Pvt. Ltd.
Research and Development - Vaccines

Available push and Pull forces

Access to Technology

Investment

Decision making matrix for vaccine R & D

Sustainability

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SII and Vaccine development

Initial focus was on EPI vaccines- were developed for both bacterial and viral vaccines.

Technological advanced products: e.g polysaccharide conjugate vaccines and recombinant vaccines. (Tech transfers played an important role).

Development of similar monoclonal antibodies (rabies launched 2017, dengue under development).

The objective is to be a world leader in the field of biosimilars. Biosimilars costs are high. The objective is to make them affordable to all.

Philosophy of SIIPL: To work on the vaccines which are needed in massive quantities and make them affordable with no compromise in quality.
SII strengths to deliver affordable vaccines

- Significant Investments in R&D and infrastructure
- Quality Management Systems
- Successful partnerships
- Skilled Human Resource
- Extraordinary abilities in process development & up-scaling operations
Build, Buy, Partner: Benefits and Tradeoffs

**Build**
- Maximum product control
- Own the IP
- Most profit opportunity
- Longer time to commercialize
- Risk in market shifts
- High development costs
- Highest switching costs

**Pros**
- Reduces time to market
- Own the IP
- Good for products with production challenges such as for Pneumococcal Conjugate vaccine

**Cons**
- Acquisition costs
- Integration costs

**Buy**
- Shortest Time to Market
- Conserves Resources
- Good model for public health goals

**Partner**
- Shared Control
- Integration Costs
- Shared gross margins

SII is a LEADING EXAMPLE OF SUCH MODELS.

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Sustainability- Challenges with EPI vaccines

- Developing country manufacturers’ business models are based on economies of scale with strengths in process engineering and process innovations.
- Business largely drives from EPI vaccine supplies to UN agencies.
- EPI vaccine prices are tightly regulated. With many competitors in scope now, price wars are imminent.
- Pricing pressure on manufacturers in near future, will further impact businesses and return investments on R & D on newer vaccines.

Expectations

- Rationalization on vaccine pricing is required.

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Sustainability- Challenges with new vaccines

- Accessibility to poorest of poor
- No compromise on safety, quality and efficacy of vaccines.
- Ever increasing cGMP expectations and costs on compliance.
- Compared to EPI vaccines, newer vaccines are challenging to develop and manufacture. Long lead times- example- Pneumococcal Conjugate Vaccine: an extremely complex vaccine to develop and manufacture.
- Push and Pull incentives come with expectations of reduced vaccine pricing.
- Rationalization of vaccine pricing- need of the hour.

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REGULATORY CHALLENGES

Serum Institute of India Pvt. Ltd.
Vaccine registration / marketing authorization is a prerequisite to introduction of vaccines in any country.

Marketing authorization evaluation, particularly for novel vaccines is challenging.

NRAs in producing and in high income countries usually have the required infrastructure and resources for a proper review.

NRAS in many user countries may not have the required conditions to conduct a meaningful evaluation of such complex products.
Regulatory constraints

- Two or three levels of regulatory approval (producing country, WHO-PQ and receiving country)
- Poor recognition of prior evaluation/s performed including WHO-PQ (focuses on DCs needs)
- Unpredictable and usually long review processes in user countries
- Diversity of requirements and dossier formats: significant regulatory affairs resources and time needed to comply with demands from different countries
- Redundant testing and inspections conducted
SII contribution in regulatory issues

- Approached DCVMN, this network in collaboration with IFPMA organized a regulatory working group to identify the magnitude of the diversity in requirements (quantification).

Working group focused on:

- Comparison of CTD dossiers from different countries to assess level of divergence or similarity
- Comparison of application forms of 8 countries
- Comparison of evaluation process in 134 countries

NOTE: Reg. Affairs experts from 10 companies (7 from DCVMN and 3 from IFPMA participate in the WG)

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Countries included in the CTD comparison exercise

✔ **Module 1 (not harmonized):** CTDs of Australia, China, Europe, the Gulf Cooperation Council (GCC), India, Jordan, PAHO, Tanzania, Thailand, the United States (US) and the (World Health Organization (WHO) are compared to each other.

✔ **Modules 2-5 (harmonized):** CTDs from ASEAN, PAHO, India, Jordan FDA and Thai FDA are compared to the ICH CTD as implemented by US FDA.

Contents and format (numbering) were compared
COMPARISON OF CTD MODULE 1 CONTENT FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO

MODULE 1: Not harmonized

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COMPARISON OF CTD MODULE 1 NUMBERING FROM AUSTRALIA, CHINA, EUROPE, GCC, INDIA, JORDAN, PAHO, TANZANIA, THAILAND, US AND WHO

MODULE 1: Not harmonized

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**CTD CONTENT: ASEAN, INDIA, JORDAN, PAHO AND THAILAND Vs. ICH (FDA)**

Overall Comparison Modules 2-5

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<td>JORDAN Vs ICH (FDA)</td>
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**MODULES 2-5: Harmonized**

- **Similar**: 20%
- **Different**: 80%
# CTD NUMBERING: ASEAN, INDIA, JORDAN, PAHO AND THAILAND Vs. ICH (FDA)

Comparing All Modules 2-5

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<td>100</td>
<td>73</td>
<td>83</td>
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**MODULES 2-5: Harmonized**

- **Same**: 17%
- **Different**: 83%
Vaccine registration process

Product registration

- Required: 106
- Accept PQ: 23
- Not known: 5

GMP inspection

- Required: 29
- Not Required: 94
- Not known: 11

Dossier format

- ICH CTD: 32
- Country Specific: 60
- ACTD: 8
- Not known: 13

Not Required: 21

Vaccine samples

- Required: 89
- Testing: 13
- Visual inspection: 3
- Not known: 73

- Not Required: 23
- Not known: 22

NR: No regulatory activity
Next steps include publication of this data and development by the WG of a proposal for improvements to be shared with stakeholders (WHO, ICH, economic blocks, etc) with support from UNICEF, GAVI, MSF, regulatory networks, etc.